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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,621	11/20/2001	Tae-Yeon Kim	0136/1E154US1	4085

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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/989,621

**Applicant(s)**

KIM ET AL.

**Examiner**

Hope A. Robinson

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Preliminary Amendment filed November 20, 2001 has been received and entered.

### ***Claim Disposition***

2. Claims 1-5 have been canceled. Claims 6-12 are pending and under examination.

### ***Abstract***

3. The abstract of the disclosure is objected to because the abstract contains legal language (see lines 12 and 15). Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 102 / 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

5. Claims 6-12 are rejected under 35 U.S.C 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chisari et al. (5,840,303, June 6, 1995).

Chisari et al. disclose a liposome (claim 6) to administer or carry a peptide with the structure EIRLKVFVL (claim 7). As the structure of the peptide is the same as the instant peptide, properties such as function is inherent. This rejection has been made as a 102/103 rejection in view of the product-by-process format of applicant's claims. The use of a 102/103 rejection for the rejection of a product-by-process claim has been approved by the courts. While the reference does not specifically disclose that the liposome is prepared by mixing phospholipid (how the phospholipid is prepares (claims 8-12)) and one or more peptides derived from X protein and the molar ratio used (claim 6), the production of the liposome by a particular process does not impart novelty or unobviousness to a peptide when the same peptide is taught by the prior art. This is particularly true when the properties of the peptide are not changed by the process in an

unexpected manner. See *In re Thrope*, 227 USPQ964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because the peptide of the reference is identical to the peptide as claimed thus is expected to exhibit the same properties, for example, function and molar weight/ratios. Further, the reference disclose that liposomes are used to administer the peptide. Additionally, page 3 of the instant specification states that "ph-sensitive liposomes have been widely used as carriers and adjuvant systems of the protein and peptide antigen for the development of subunit vaccine". Finally, as the claim is written in a product-by-process format and the claimed process does not appear to change the properties of the product in an unexpected manner, the claimed invention was within the skill of the art and is *prima facie* obvious.

6. Claims 6-12 are rejected under 35 U.S.C 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Readdy et al. (J. Immunol. Methods, vol. 141, no. 157, 1991) in view of Grey et al. (WO 94/20127, September 15, 1994).

Readdy et al. disclose a pH-sensitive liposome used as a carrier or adjuvant system for a protein or peptide antigen for the development of subunit vaccine (claim 6). This rejection has been made as a 102/103 rejection in view of the product-by-process format of applicant's claims. The use of a 102/103 rejection for the rejection of a

product-by-process claim has been approved by the courts. Readdy et al. does not teach the structure of the peptides as claimed, however, Grey et al. disclose the peptides with the structures VLHKRTLGL and CLFKDWEEL. As the structure of the peptide is the same as the instant peptide, the function claimed is an inherent property. In-so-far-as the references do not specifically disclose that the liposome is prepared by mixing phospholipid (how the phospholipid is prepares (claims 8-12)) and one or more peptides derived from X protein and the molar ratio used (claim 6), the production of the liposome by a particular process does not impart novelty or unobviousness to a peptide when the same peptide is taught by the prior art. This is particularly true when the properties of the peptide are not changed by the process in an unexpected manner. See *In re Thrope*, 227 USPQ964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole by combining the teachings of the references because Readdy et al. teach liposomes used to carry peptides and Grey et al. teach peptides that are identical to the peptides as claimed thus is expected to exhibit the same properties, for example, function and molar weight/ratios. Additionally, as the claims are written in a product-by-process format and the claimed process does not appear to change the properties of the product in an unexpected manner, the claimed invention was within the skill of the art and is *prima facie* obvious.

**Conclusion**

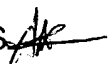
7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS   
Patent Examiner



ROBERT A. WAX  
PRIMARY EXAMINER